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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/831,272	08/13/2001	Christoph Kirsch	9730.001	3234

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EXAMINER

MARVICH, MARIA

ART UNIT	PAPER NUMBER
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1633

MAIL DATE	DELIVERY MODE
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11/20/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/831,272

Applicant(s)

KIRSCH ET AL.

Examiner

Maria B. Marvich, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-40 and 42-49 is/are pending in the application.
- 4a) Of the above claim(s) 1,4-7,10-21,23-38 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 2,3,22,39 and 42-49 is/are rejected.
- 7) ☒ Claim(s) 8, 9 and 43-45 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Claims 1-40 and 42-49 are pending in the instant application. Claims 1, 4-7, 10-21, 23-38 and 40 are withdrawn and therefore, claims 2, 3, 8, 9, 22, 39 and 42-49 are under examination

Claim Objections

Claims 2, 3, 39, 42 and 43 are objected to because of the following informalities: claims 2, 3, 42, 47, 48 and 49 recite "chimeric promoter capable of mediating local gene expression in plants upon pathogen infection.". First, use of the phrase "capable of mediating" does not indicate the direct relationship between inductive conditions and expression. Secondly, in claims 2 the conclusion is that "said local gene expression upon elicitor treatment or pathogen infection". However, elicitor treatment is not one of the contemplated treatments as set forth in the preamble. It would be remedial to recite -- chimeric promoter capable of local gene expression in plants wherein expression is induced by elicitor treatment or pathogen infection --.

Claim 39 recites in line 5 "the combination of one copy of SEQ ID NO:11 and one copy of SEQ ID NO:7". It is customary to use the article "the" or "said" when referring to previous limitations in the claims. In this case, it would be remedial to amend the claim to recite --a combination--.

In claim 42, the claims use both "the" and "said" when referencing the previous limitations. Both are redundant and unnecessary. It would be remedial to delete either "the" or "said". As well, in claim 43, the recitation of "at least one of the said two or more cis-acting elements" is confused by its being 4 elements, 2 of SEQ ID NO:11 and 2 of SEQ ID NO:7. It

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would be clearer if the claims simply recited --wherein the two or more cis-acting elements comprise--.

Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2, 3, 22, 39, 42, 47 and 49 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an element sufficient for induction of pathogen elicitor expression, does not reasonably provide enablement for any other embodiment. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims. **This is a new rejection.**

The test of enablement is whether one skilled in the art could make and use the claimed invention from the disclosures in the patent coupled with information known in the art without undue experimentation (*United States v. Telectronics, Inc.*, 8 USPQ2d 1217 (Fed. Cir. 1988)). Whether undue experimentation is required is not based on a single factor but is rather a conclusion reached by weighing many factors (See *Ex parte Forman*, 230 USPQ 546 (Bd. Pat. App. & Inter, 1986) and *In re Wands*, 8USPQ2d 1400 (Fed. Cir. 1988); these factors include the following:

The instant claims are drawn to a chimeric promoter comprising *cis*-elements “sufficient to direct elicitor specific expression”. However, the claim does not set forth what type of elicitor and hence the use of the term “specific” is inaccurate as elicitor is a genetic term and not all elicitors have been demonstrated to activate expression from the disclosed SEQ ID NO:s. The specification teaches that SEQ ID NO:11 and 7 are activated by pep25, which is a pathogen obtained elicitors. So while the conditions recited for expression from the elements is high, the only disclosed elicitors that are capable of mediating induction through SEQ ID NO:11 or 7 are fungal or pathogen elicitors. It is highly unpredictable based upon the teachings of the instant specification that condition will lead to these increased levels of induction.

The specification teaches that elicitors capable of activating the instant elements can be identified. However, naming a type of material generically known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. When one is unable to envision the detailed constitution of a complex chemical compound having a particular function, such as an elicitor, so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the nucleic acid has been isolated. Thus, claiming all elicitors that achieve a result without defining what means will do so is not in compliance with the description requirement. Rather, it is an attempt to preempt the future before it has arrived.

Given the lack of guidance in the specification, the large and diverse group of inducible conditions that are recited and the highly unpredictable nature of the ability to predict those that mediate through SEQ ID NO:11 induction of local gene expression, it is concluded that a person

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of skill in the art would have had to conduct undue experimentation in order to practice the claimed

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 48 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van de Locht et al (EMBO J, 1990, vol 9(9) p 2945-2950; see entire document) in view of Pears and Williams (Nucleic Acids Research, 1988, Vol 16(17), pages 8467-84861; see entire document) and Searle et al, MCB, 1985, Vol 5(6), pages 1480-1489; see entire document) further in view of Comai et al (Plant Molecular Biology, 1990, Vol 15(3), pages 373-381; see entire document). **This is a new rejection necessitated by applicants' amendment.**

Applicants claim a chimeric promoter comprising two copies of SEQ ID NO: 11.

Van de Locht et al teach a promoter obtainable by insertion of pPR2-10, which comprises at least one cis-acting element sufficient to direct elicitor-specific expression into the promoter of the GUS reporter gene. pPR2-10 comprises SEQ ID NO:11 (nucleotides -77 to -46) as indicated in figure 5, which demonstrates that pPR2-10 comprises the region from -168 to -43. This region comprises SEQ ID NO: 11 and functions as a cis-element sufficient to direct elicitor specific expression with the CAAT element. The promoter of van de Locht et al as disclosed in Figure 5 and 6 is a chimeric promoter formed by fusion of parsley chalcone synthase promoter (which

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provides the minimal promoter) to a PR2 fragment. Van de Locht et al do not teach that pPR2-10 comprises two copies of the elicitor element.

Pears and Williams teach that heterologous promoter sequences inserted into promoters can mediate sufficient gene expression (see e.g. abstract). Specifically, Pears and Williams teach that the promoter elements function "optimally" when multiple copies of the sequences are present (see e.g. page 8480 and figure 7).

Searle et al teach that promoters comprising two heterologous inducible elements isolated from the methallothionein I gene function as strong inducible promoter, whereas a single element did not respond to zinc (see e.g. abstract). Applicants reason that more than two should further increase the inducibility of the promoter.

Comai et al teach that promoters can be duplicated with the effect of enhanced expression (see e.g. abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to duplicate the isolated promoter fragment that is elicitor responsive as taught by van de Locht et al as taught by Pears and Williams and Searle et al and Comai et al because and van de Locht et al teach that a fragment of the PR2 promoter is responsible for strong elicitor mediated gene activation and because Pears and Williams and Searle et al teach that multiple elements are more effective than single elements and Comai et al teach that it is within the ordinary skill of the art to generate chimeric vectors in which larger promoter elements are duplicated. One would have been motivated to do so in order to receive the expected benefit of enhanced regulation of heterologous genes. Based upon the teachings of the cited references, the

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high skill of one of ordinary skill in the art, and absent evidence to the contrary, there would have been a reasonable expectation of success to result in the claimed invention.

Conclusion

Claims 2, 3, 22, 39, 42 and 47-49 are rejected.

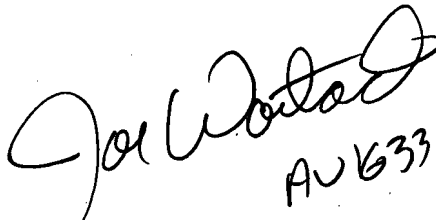
Claims 8, 9, 43-45 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maria B. Marvich, PhD whose telephone number is (571)-272-0774. The examiner can normally be reached on M-F (7:00-4:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, PhD can be reached on (571)-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Maria B Marvich, PhD
Examiner
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